

1 (Currently amended): A unitized electronic time-temperature indicator device for rapidly assessing the acceptability of a material's thermal history, said device containing computational means, and a temperature measurement means; wherein said device periodically samples the temperature and computes a function of temperature that is continually operative throughout the relevant temperature monitoring range of the device; and wherein said function of temperature approximates the impact that the relevant temperature, for that period's length of time, has on a detectable property of said material; and wherein said computational ~~computing~~ means generate a running sum of said function of temperature over time; and wherein said function of temperature resides with said unitized device; and wherein the granularity of the function of temperature is small enough, and the frequency of time measurements is often enough, as to substantially approximate the impact of time and temperature on the detectable property of said material; and in which said running sum is compared to a reference value, and the result of said comparison is used to generate an output signal indicative of the fitness for use of said material.

2 (Original): The method of claim 1, in which said function of temperature is in the form of a multi-element lookup table or set of equation parameters that is capable of rendering complex temperature functions that cannot be adequately modeled by a single exponential Arrhenius equation.

3 (Original): The device of claim 1, in which the output signal is chosen from the group of visual output signals, vibration signals, sonic signals, radiofrequency signals, electrical signals, or infra-red signals.

4 (Original): The device of claim 1, further containing means to enable the function of temperature and reference value to be automatically programmed into an assembled device.

5 (Original): The device of claim 1, in which the computational means is a microprocessor, the device is continually powered throughout its use lifetime, and the power means is chosen from the group of battery, storage capacitor, thermal, photoelectric, AC power, or radio frequency means.

6 (Original): The device of claim 1, in which the function of temperature has a temperature resolution granularity of 10 °C or smaller, and the periodicity of sampling has a time resolution granularity of 2 hours or smaller.

7 (Original): The device of claim 1, in which the function of temperature is stored in the form of a lookup table that has a separate table entry for every temperature throughout the measuring range of the device, and in which each table entry spans a temperature range of 2 °C or less.

8 (Currently amended): The device of claim 1, in which the display output signal means convey information pertaining to the fractional remaining stability lifetime of material that has not yet expired, or the fractional completion of a time-temperature dependent incubation reaction.

9 (Original): The device of claim 1, further containing a temperature logger that records data pertaining to the temperature history of the device, wherein the output signal is used to either stop the logger, so that the logger records only data pertaining to the temperature history prior to material expiration, or alternatively place a mark in the logger, so that the data obtained prior to material expiration can be easily segregated from data obtained after material expiration.

10 (Original): The time-temperature device of claim 1, incorporated into a material dispensing device, in which the time-temperature device signals if the material should be dispensed or not depending upon the acceptability of the material's thermal history.

11 (Currently amended): A unitized electronic time-temperature indicator device for rapidly assessing the acceptability of a material's thermal history, said device containing computational means, and a temperature measurement means; wherein said device periodically samples the temperature and computes a function of temperature that is continually operative throughout the relevant temperature monitoring range of the device; and wherein said function of temperature is in the form of a multi-element lookup table or set of equation parameters that is capable of rendering complex temperature functions that cannot be adequately modeled by a single exponential Arrhenius equation; and wherein said function of temperature approximates the impact that the relevant temperature, for that period's length of time, has on a detectable property of said material; and wherein said computational ~~computing~~ means generate a running sum of said function of temperature over time; and wherein said function of temperature resides with said unitized device; and wherein the granularity of the function of temperature is small enough, and the frequency of time measurements is often enough, as to substantially approximate the impact of time and temperature on the detectable property of said material; and in which said running sum is compared to a reference value, and the result of said comparison is used to generate a visual output indicative of the fitness for use of said material, and the device contains means to allow the function of temperature and reference value to be automatically programmed into an assembled device.

12 (Original): The device of claim 11, in which the function of temperature and reference value may be programmed into the assembled device by a replaceable memory chip, electronic data transfer, infrared data transfer, or radio frequency data transfer.

13 (Original): The device of claim 11, further containing a temperature logger that records data pertaining to the temperature history of the device, wherein the output signal is used to either stop the logger, so that the logger records only the temperature history prior to material expiration, or alternatively place a mark in the logger, so that the

temperature data obtained prior to material expiration can be easily segregated from temperature data obtained after material expiration.

14 (Original): The device of claim 11, in which the computational means is a microprocessor, the device is continually powered throughout its use lifetime, and the power means is chosen from the group of battery, storage capacitor, thermal, photoelectric, AC power, or radio frequency means.

15 (Original): The device of claim 11, in which the function of temperature has a temperature resolution granularity of 10 °C or smaller, and the periodicity of sampling has a time resolution granularity of 2 hours or smaller.

16 (Original): The device of claim 11, in which the display means convey information pertaining to the fractional remaining stability lifetime of material that has not yet expired, or the fractional completion of a time-temperature dependent incubation reaction.

17 (Original): The time-temperature device of claim 11, incorporated into a material dispensing device, in which the time-temperature device signals if the material should be dispensed or not depending upon the acceptability of the material's thermal history.

18 (Currently amended): A method for monitoring the storage life of materials: said method consisting of:
modeling the thermal degradation characteristics of the material as a function of temperature and time based upon a plurality of experimental data points;
using the time-temperature parameters from this model to program a unitized electronic time-temperature indicator device to automatically assess the acceptability of a material's thermal history;
said device containing computational means, and a temperature measurement means;

wherein said device periodically samples the temperature and computes a function of temperature that is continually operative throughout the relevant temperature monitoring range of the device;

and wherein said function of temperature approximates the impact that the relevant temperature, for that period's length of time, has on a detectable property of said material;

and wherein said computational computing means generate a running sum of said function of temperature over time;

and wherein said function of temperature resides with said unitized device;

and wherein the granularity of the function of temperature is small enough, and the frequency of time measurements is often enough, as to substantially approximate the impact of time and temperature on the detectable property of said material;

and in which said running sum is compared to a reference value, and the result of said comparison is used to generate an output signal indicative of the fitness for use of said material.

19 (Currently amended): The method of claim 18, in which the materials are selected from the group consisting of food, chemicals, biotherapeutics, vaccines, drugs, medical diagnostics, blood, blood products, cut flowers, and post harvest agricultural materials.

20 (Original): The method of claim 18, in which the device remains associated with the material throughout the majority of the material's storage life.

21 (Currently amended): The method of claim 19, in which said function of temperature is in the form of a multi-element lookup table or set of equation parameters that is capable of rendering complex temperature functions that cannot be adequately modeled by a single exponential Arrhenius equation.

22 (New): The device of claim 1, further containing a temperature logger that records data pertaining to the temperature history of the device, wherein said output signal is used to either stop the logger, so that the logger records only data pertaining to the temperature history prior to material expiration, or alternatively place a mark in the logger, so that the

data obtained prior to material expiration can be easily segregated from data obtained after material expiration,
and where, upon interrogation of the status of said device, the device outputs a status signal consisting of at least said fitness for use output signal, and at least some of said temperature logger data pertaining to the temperature history prior to material expiration, and the time elapsed since material expiration.

23 (New): The device of claim 1, further containing a temperature logger that records data pertaining to the temperature history of the device, wherein the output signal is used to either stop the logger, so that the logger records only data pertaining to the temperature history prior to material expiration, or alternatively place a mark in the logger, so that the data obtained prior to material expiration can be easily segregated from data obtained after material expiration,

in which said temperature logger operates in a loop in which the earliest temperature entries are continually updated with more recent temperature entries, and in which said updating stops upon initially receiving said output signal indicating that said material is no longer fit for use,

and where, upon interrogation of the status of said device, the device outputs a status signal consisting of at least said fitness for use output signal, and at least some of said temperature logger data pertaining to the temperature history prior to material expiration, and the time elapsed since material expiration.

24 (New): The device of claim 1, further containing a temperature logger that records data pertaining to the temperature history of the device, wherein said output signal is used to either stop the logger, so that the logger records only data pertaining to the temperature history prior to material expiration, or alternatively place a mark in the logger, so that the data obtained prior to material expiration can be easily segregated from data obtained after material expiration,

and where, upon interrogation of the status of said device, the device outputs a status signal consisting of at least said fitness for use output signal, and at least some of said temperature logger data pertaining to the temperature history prior to material expiration,

and the time elapsed since material expiration, and an optional identification code, said status signal being a radiofrequency signal.

25 (New): The device of claim 1, in which said device contains additional sensors selected from the group consisting of humidity sensors, ethylene oxide sensors, or sensor for other environmental condition that impacts the fitness for use lifetime of said material.